IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

GLENDA MCCOY, and JOHN ROBERT MCCOY, themselves as PLAINTIFFS, and on behalf of decedents JON ANDREA ROBERTS, MICAYLA ROBERTS AND DYLAN ROBERTS, Plaintiff, v. PFIZER, INC, and GREENSTONE PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 4:09cv496 JUDGE: MICHAEL H. SCHNEIDER

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH SUPPORTING AUTHORITIES

Table of Contents

Table of Authorities

Statutes and Rules

Other Authorities

Defendants Pfizer Inc ("Pfizer") and Greenstone LLC ("Greenstone") (collectively "Defendants"), pursuant to Rule 56 of the Federal Rules of Civil Procedure, move for summary judgment on two alternative grounds. For the reasons set forth below, this Court should grant Defendants' motion and enter summary judgment in their favor.

STATEMENT OF THE ISSUES

1. Whether Plaintiffs' inability to adduce scientific evidence establishing general causation under the substantive standards set forth in *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997) and *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256 (Tex. 2011) requires the granting of summary judgment in favor of Defendants.

2. Does the learned intermediary doctrine defeat Plaintiffs' claims, which are based on an alleged failure to warn, where there is no evidence to rebut the statutory presumption that the FDA-approved warning was adequate and the prescribing physician admits that he was fully aware of the risks associated with the drug when he prescribed it?

PROCEDURAL HISTORY

Plaintiffs claim that their adult daughter, Jon Andrea Roberts ("Ms. Roberts") murdered her husband and two children and then committed suicide as a result of her use of sertraline, a generic antidepressant medication manufactured by Greenstone, which Ms. Roberts had been prescribed in the first instance by physicians for treatment of anxiety and depression. Plaintiffs, who are Ms. Roberts' parents, brought suit individually and on behalf of the estates of their daughter and grandchildren against Defendants under the Texas Wrongful Death and Survival Acts seeking actual and punitive damages based on products liability, negligence, breach of warranty, and the Texas Deceptive Trade Practices Act. (Dkt. #77). Defendants filed a Rule

12(c) Motion for Dismissal Due to Lack of Standing and Rule 56 Motion for Partial Summary Judgment Due to Lack of Capacity (Dkt #28). The Court granted in part and denied in part this motion, dismissing: (1) all claims under the Texas Deceptive Trade Practices Act; (2) all wrongful death claims except for Plaintiffs' wrongful death claim for compensatory damages based on the death of their daughter, Ms. Roberts; (3) and Plaintiffs' claim for punitive damages for the wrongful death of their daughter. (Dkt. #43 and 44). Defendants filed a second motion for partial summary judgment on survivorship claims based on lack of capacity because Plaintiffs had not been designated as the personal representatives of the estates of Ms. Robert or Dylan and Micayla Roberts and therefore lacked capacity to assert survival claims on behalf of their estates. (Dkt #54). The Court denied this motion. (Dkt. #64 and #72).

Accordingly, only the following claims remain: (1) the McCoys' wrongful death claim for the death of their daughter, Andrea; (2) the McCoys' survival claims on behalf of the estates of Micayla and Dylan Roberts; and (3) the McCoys' survival claim on behalf of the estate of Andrea Roberts. (Dkt. #43 and 44). The bases of these claims are: defective design, failure to warn, breach of warranty, and negligence.

STATEMENT OF UNDISPUTED FACTS

1. On July 30, 2007, Ms. Roberts shot and killed her husband and two children, and committed suicide. (Dkt. #77 ¶ 12.)

2. Plaintiffs claim that Defendants caused these events by failing to warn Ms. Roberts or her physician regarding the safety and efficacy of Zoloft, which had been

prescribed for Ms. Roberts on July 24, 2007—less than a week before the incident—by her family practitioner, Dr. Brian Glaser. (Dkt. #77[1] ¶68.)

FDA's Finding That Antidepressants Do Not Increase the Risk of Suicide in Adults

3. In November 2006, months before Ms. Roberts killed her family and herself, FDA completed the largest and most comprehensive analysis yet conducted of the clinical data for antidepressants to ascertain whether there is any increased risk of suicidal thoughts or behaviors associated with antidepressant use in adults. (*See* Stone and Jones, Clinical Review: Relationship Between Antidepressant Drugs and Suicidality in Adults (Nov. 17, 2006) ("Stone and Jones"), Ex. 1.)[2]

4. In its 2006 analysis, FDA compiled and evaluated data from double-blind, randomized, controlled clinical trials of sertraline and other antidepressants, including, in particular, comparison of the incidence of suicidal behavior (even including mere thoughts of suicide) between patients who had been treated with sertraline or other antidepressant medications within the same general class (selective serotonin reuptake inhibitors, or SSRIs) and similar patients who had been administered an inactive sugar pill (placebo). (*See* Stone and Jones at 6 ("This review examines the relationship between antidepressant drugs and suicidality in adult subjects, as assessed within randomized, placebo-controlled trials for various indications.").)[3]

---

[1] This is the second pleading titled, "Second Amended Complaint" on file for Plaintiffs. Defendants are referring to Plaintiffs' Second Amended Complaint, Docket No. 77.

[2] Citations in the form "Ex. __" are to the exhibits to the Declaration of Kurt Halvorsen, filed concurrently herewith.

[3] As stated in the Reference Manual for Scientific Evidence, "[t]his type of study, called a randomized trial, clinical trial, or true experiment, is considered the gold standard for

5. For antidepressants generally, FDA's analysis showed that the odds ratio[4] for "ideation or worse" (i.e., suicidal thoughts, gestures, attempts, and completed suicides) was 0.83, indicating 17% lower risk of suicidal thoughts and actions in adult patients treated with antidepressants than in those treated with placebo. (*See* Stone and Jones at 24, table 15.) Thus, adult clinical trial subjects experienced suicidal thoughts and actions more often when they were given sugar pills than when they were given the medications that Plaintiffs claim cause suicide.

6. For Zoloft specifically, the data—drawn from 60 separate clinical studies involving more than 11,000 patients—showed a strong ***protective effect***, with a statistically significant odds ratio of 0.51, indicating that there was approximately half the risk of suicidal thoughts and actions in adult patients treated with Zoloft as in patients given a placebo. (*Id*.)

7. The Zoloft-specific data for actual suicidal behaviors (excluding mere suicidal thoughts) were still more reassuring, with a statistically significant odds ratio of 0.25, indicating that one fourth as many suicidal behaviors occurred in Zoloft exposed adult patients. (*Id*. at 26, table 16.)

---

determining the relationship of an agent to a health outcome or adverse side effect." Ref. Man. Scientific Ev. 3d Ed. at 555.

[4] The results of FDA's analysis are expressed by a statistical measurement called the odds ratio, which is simply the ratio of the odds that a patient with suicidality was treated with a medication to the odds that such a patient was treated with an inactive sugar pill. *Havner*, 953 S.W.2d at 721; s*ee also* Ref. Man. Scientific Ev. 3d Ed. at 568-69. An odds ratio of 1.0 thus indicates equivalent risk between drug and placebo, an odds ratio larger than 1.0 indicates increased risk in drug-treated patients, and an odds ratio less than 1.0 indicates decreased risk in drug-treated patients, compared to placebo. *Id.* For rare events like suicide, the odds ratio is a close approximation of the relative risk—the risk measure addressed in *Havner* and *Garza*. *Id.*

8. FDA concluded that there is no increased risk of suicide for adult patients treated with any antidepressant, and that "the most consistent finding is an odds ratio for sertraline that is lower than for other drugs, both SSRI and non-SSRI." (*Id*. at 39.)

9. As a result of these findings, FDA in May 2007 mandated revised labeling for all antidepressants (commonly referred to as "class labeling") reflecting the absence of evidence of any increase in suicide risk for patients above age 24:

> Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies ***did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24***; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older.

(*See* U.S. Zoloft Labeling (June 2007) at 2576, Ex. 2 (emphasis added).)

10. Numerous epidemiological studies have reached conclusions similar to FDA's, finding no increased risk of suicidality associated with adult use of sertraline and other SSRIs. (*See, e.g.*, C. Barbui et al. *Selective Serotonin Reuptake Inhibitors and Risk of Suicide: A Systematic Review of Observational Studies*, 180 Canadian Med. Assoc. J. 291 (2009) ("Based on data from observational studies, use of SSRIs may be associated with a reduced risk of suicide in adults with depression.") (Ex. 3); R. Gibbons et al. *Relationship Between Antidepressants and Suicide Attempts: An Analysis of the Veterans Health Administration Data Sets*, 164 Am. J. Psychiatry 1044 (2007) ("These findings suggest that SSRI treatment has a protective effect in all adult age groups. They do not support the hypothesis that SSRI treatment places patients at greater risk of suicide.") (Ex. 4); R.J. Valuck et al. *Antidepressant Treatment*

and Risk of Suicide Attempt by Adolescents with Major Depressive Disorder, 18 CNS Drugs 1119 (2004) ("Antidepressant medication use had no statistically significant effect on the likelihood of suicide attempt in a large cohort of adolescents across the US after propensity adjustment for treatment allocation and controlling for other factors.") (Ex. 5.)

Plaintiffs' Expert Confirms That No Study Establishes a Doubling of Risk for Suicide or Homicide Associated With Sertraline

11. Plaintiffs have designated a psychiatrist, Dr. George Glass, to opine on general causation in this case. (*See* Rpt. of Dr. G. Glass, Ex. 6.) Although Dr. Glass relies on numerous publications in his report, none of them reports the results of an epidemiological study finding a statistically significant doubling of the risk of either homicide or suicide associated with sertraline use in adults. (*Id.*)

12. Dr. Glass admitted at deposition that he cannot identify any study finding a statistically significant doubling of risk for suicide or homicide associated with Zoloft. (Deposition of Dr. G. Glass ("Glass Dep.") at 148:5-11; 237:12-17, excerpts attached as Ex. 7.)

13. Dr. Glass further admitted that he relies primarily on uncontrolled case reports to support his opinion that Zoloft can cause suicide and homicide. (*Id.* at 160:16-23.)

Ms. Roberts' Troubled History

14. Long before Andrea Roberts was prescribed sertraline, she endured verbal and physical abuse from her father and husband. Throughout her childhood, Andrea Roberts suffered verbal abuse and physical intimidation at the hands of her father. (Dep. John A. McCoy 59:14-16, excerpts attached as Ex. 8). Her father would "go into fits and rages sometimes when he was upset and he would punch holes in walls and break TV trays." (*Id*. at 56:19-22). In one instance, when Andrea was in the ninth grade, her father kicked in her door and yelled at her. (*Id*. at

65:15-66:9); (Pl.'s Resp. to Def.'s Req. for Admis. No. 73); (Pl.'s Resp. to Def.'s Interrog. No. 24).

15. Andrea did not escape abuse in her marriage. Her husband, Michael, was both physically and psychologically abusive. (Dep. Jill Dawson 123:15-124:6, excerpts attached as Ex. 9). On New Year's Eve of 2006-07, the police were contacted because Andrea had been physically assaulted and injured by her husband. (*Id* at 122:11-124:6). Sometimes, Andrea's husband would force her to "watch porn with him and then act out porn." (*Id*. at 66:5-9).

Ms. Roberts' Financial Difficulties

16. By 2007, Andrea and her husband were experiencing significant financial difficulties. They had accumulated over $29,000 in credit card debt, and Michael Roberts owed at least $25,000.00 in conjunction with his business. (Flower Mound Police Department Investigative Report, Detective Sullivan, Ex. 10).

17. The Roberts' financial situation came to a head in 2007 when Andrea learned that she and her husband owed over $290,000.00 to the IRS because of their failure to pay taxes for several years. (Dep. of Glenda McCoy 43:1-5; 187:3-6, Ex. 11); (Notice of Federal Tax Lien, Instrument Number/Book & Page 2008E0116155, Ex. 12); Notice of Federal Tax Lien, Instrument Number/Book & Page 2008E0116156, Ex. 13). Around March, Andrea exhibited "a lot of anxiety and stress" that was "attributed to health issues, Michael's mother Marcia, and money owed to the IRS." (Flower Mound Police Department Investigative Report, Detective Sullivan, Ex. 10).

Ms. Roberts Begins Expressing Delusional Thoughts About Her Health

18. It was also in 2007 that Andrea began expressing delusional thoughts about her health. (*Id*. at 115:8-16) (Flower Mound Police Department Investigative Report, Detective Sullivan, Ex. 10). On June 21, 2007, Andrea visited her OB/GYN, Dr. Rakesh Gupta, fearing that she had herpes. (Dep. of Rakesh Gupta 29:6-30:10, excerpts attached as Ex. 14.). Andrea was tested, and the results came back negative. (*Id*. at 31:22-24). Seven days later, on June 28, 2007, Andrea called Dr. Gupta and told him that she was experiencing significant anxiety. (*Id*. at 33:5-34:1). Dr. Gupta phoned in a prescription for Xanax, an antianxiety medicine, in response. (*Id*. at 34:2-4).

19. On July 5, 2007, Andrea returned to Dr. Gupta's office for a follow-up exam. (*Id*. at 34:14-22). That day, she told Dr. Gupta that she was experiencing vaginal swelling and heavy periods, but her physical exam revealed no abnormalities. (*Id*. at 35:3-5). She also asked Dr. Gupta to test her for gonorrhea and chlamydia. (*Id*. at 35:6-8). When Dr. Gupta asked her why she wanted these tests, Andrea refused to give a reason. (*Id*.). Andrea's tests again came back negative. (*Id*. at 36:19-37:2).

20. On July 7, 2007, Andrea visited her family practitioner, Dr. Brian Glaser, complaining of a rash and sore throat. (Dep. of Dr. Glaser 68:24, excerpts attached as Ex. 15.). Dr. Glaser tested her for strep throat. (*Id*. at 70:7-16). This test came back negative, and Dr. Glaser was unable to determine whether she actually had a rash. (*Id*. at 70:7-19).

Ms. Roberts is Prescribed Sertraline on July 24, 2007

21. On July 24, 2007, Andrea returned to see Dr. Glaser, claiming that she "has not been feeling well and [she] has felt uptight…tired and run down" and has felt "some depression

as well" and that this "has gone on for a while." (*Id*. at 78:5-12). After conducting a physical examination, Dr. Glaser prescribed thirty 50 mg Zoloft tablets and instructed Andrea to start by taking only half of each tablet. (*Id*. at 76:10-14; 87:4-6; 101:10-15). This starting dose was at the lowest end of the approved, recommended adult dosage ranges for panic disorder (25-200 mg/day) and depression (50-200 mg/day). (Zoloft Label at 36, Ex. 16.) Andrea never told Dr. Glaser that she was already taking Xanax. (*Id*. at 82:1-83:5).

22. Later that day, Roberts filled her subscription for sertraline at a local pharmacy. (*See* Records of Tom Thumb Pharmacy, Ex. 18.) Roberts received 30 50 mg. tablets of generic sertraline manufactured by Greenstone. (*Id.*)

23. Sertraline is the generic form of Zoloft®, a proprietary form of sertraline manufactured by Pfizer Inc. (*See* Zoloft Label at 1.)

Zoloft/Sertraline Warning in July 2007

24. The U.S. professional prescribing information (also commonly referred to as the "product insert" or "labeling") that was approved by FDA and required to accompany Zoloft/sertraline at the time Roberts was prescribed sertraline in July 2007 contained the following warning:

> **Clinical Worsening and Suicide Risk**
>
> Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders.

(Zoloft Label, pg. 14, Ex. 16).

25. This warning reflected Dr. Glaser's understanding of the risks associated with sertraline, and, according to Dr. Glaser, "appropriately conveyed to [him] the information required to make an appropriate risk/benefit analysis concerning Zoloft." (Dep. of Dr. Glaser 45:8-24; 91:18-22, Ex. 15).

26. The label also contained a black box warning regarding Suicidality in Children and Adolescents, which provided in part:

> Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

(Zoloft Label, pg. 1, Ex. 16).

27. Dr. Glaser understood that adult patients should be observed just the same as pediatric patients when they were initiated on Zoloft. (Dep. of Dr. Glaser 47:11-15, Ex. 15). In fact, it was his regular practice to closely observe all patients for clinical worsening or suicidality when they were initiated on Zoloft. (*Id.* at 48:1-4; 10-19.)

28. In addition to having the information from the warning, Dr. Glaser also had extensive knowledge and experience in prescribing Zoloft. He had prescribed Zoloft "hundreds" of times over his career and had found it to be a useful medication for treating anxiety. (*Id*. at 52:9-53:1.) Dr. Glaser also kept up with the health advisories related to Zoloft and had discussions with other doctors about the drug. (*Id*. at 38:4-39:13.) Dr. Glaser continues to prescribe Zoloft for appropriate patients and believes his decision to prescribe it for Ms. Roberts was an appropriate decision. (*Id*. at 59:18-20; 89:12-16.) He has not learned anything since July

2007 that gives him any reservations about his decision to prescribe Zoloft for Ms. Roberts. (*Id*. at 89:17-21.)

29. On July 24, 2007, the same day Dr. Glaser prescribed Zoloft, at 10:00 p.m., Ms. Roberts called Dr. Gupta with yet another baseless fear that she was ill; she told him that she thought she had toxic shock syndrome. (Dep. of Dr. Gupta 37:16-38:6, Ex. 14).

30. The next day Dr. Gupta examined Ms. Roberts and concluded that she did not have toxic shock syndrome. (*Id*. at 38:7-12). Ms. Roberts also asked to be tested for hepatitis and HIV. (*Id* at 38:24-39:3). When asked why she wanted these tests, Ms. Roberts was "very upset" and "vague" and did not give a reason. (*Id*. at 39:4-24). As before, all of Ms. Roberts's tests came back negative. (*Id*. at 42:4-12). During this office visit, Ms. Roberts did not inform Dr. Gupta that she recently started taking Zoloft nor did she express the same complaints of feeling tired, run down and depressed as she did to Dr. Glaser the day before. (*Id*. at 41:18-42:1).

Ms. Roberts Kills Her Family And Commits Suicide

31. On July 30, 2007, Ms. Roberts shot and killed her husband Michael; and two children, Micayla and Dylan. (Dkt. #77 ¶ 12.)

32. In her suicide note Ms. Roberts stated, "I couldn't face what lie (sic) ahead and we don't have the money to make up (sic) feel better. I'm sorry I let you down. Growing up wasn't the easiest for me and I probably needed some major professional help." (Suicide Note to Glenda McCoy, Ex. 17).

33. Ms. Roberts was 41 years old at the time of her death. (Dep. of Glenda McCoy 24:15-16, Ex. 11).

ARGUMENT

I. LEGAL STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is "appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Smith v. Am. Family Life Assur. Co. of Columbus*, 584 F.3d 212, 215 (5th Cir. 2009) (quoting Fed. R. Civ. P. 56(c)) (internal quotations omitted). Once the moving party "meets its initial burden of pointing out the absence of a genuine issue for trial, the burden is on the nonmoving party to come forward with competent summary judgment evidence establishing the existence of a material factual dispute." *Id.* (citation omitted). Rule 56 requires entry of judgment "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Versai Mgmt. Corp. v. Clarendon Am. Ins. Co.*, 597 F.3d 729, 735 (5th Cir. 2010) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

II. PLAINTIFFS' FAILURE TO ADDUCE SCIENTIFIC EVIDENCE OF GENERAL CAUSATION REQUIRES SUMMARY JUDGMENT FOR DEFENDANTS

Under Texas law, to prevail on their claims, Plaintiffs must prove, *inter alia*, both (i) that sertraline can cause people to commit homicide and suicide (general causation) and (ii) that sertraline, as opposed to another cause or set of causes, caused Roberts to commit homicide and suicide (specific causation). *See, e.g., In re Norplant Contraceptive Products Liability Litigation*, 215 F. Supp. 2d 795, 830 (E.D. Tex. 2002); *Owens v. American Home Prods. Corp.*, 2005 WL 1657036 at *2 (S.D. Tex. July 12, 2005) (collecting cases).

The Texas Supreme Court, in *Havner* and *Garza*, has held that a plaintiff must present at least two reliable epidemiological studies finding a statistically significant doubling of risk of the outcome at issue to establish a material issue of general causation for trial. As shown below, Plaintiffs have not, and cannot, meet this minimal requirement; in fact, they are unable to adduce even one scientific study that purports to have found any increased risk, much less a statistically significant doubling of risk, for either suicide or homicide in any group of patients. The most reliable data that address the alleged causal relationship at the heart of their claims—the results of multiple, randomized, double blind, placebo controlled trials—demonstrate that, to the extent there is any relationship at all between use of sertraline and homicide or suicide in adult patients such as Ms. Roberts, it is that sertraline ***reduces*** the risk of those acts in patients treated with the medication. In short, the claims in this case are not merely devoid of the requisite scientific support, but fly in the face of the large body of pertinent peer-reviewed scientific data. Accordingly, Plaintiffs cannot sustain their burden to present causation evidence under *Havner*/*Garza*, and Defendants are entitled to summary judgment.

A. The *Havner*/*Garza* Standard

In *Havner*, the Texas Supreme Court addressed the question of whether evidence presented by plaintiffs alleging that birth defects in their child had been caused by Bendectin was "scientifically reliable and thus some evidence to support the judgment in their favor." 953 S.W.2d at 711. In answering this question, the court set forth several specific requirements for scientific evidence to support a judgment under Texas law. The United States District Court for the Northern District of Texas has succinctly summarized the *Havner* court's holdings:

> The [*Havner*] court held, that at a minimum, for an epidemiological study to constitute evidence of causation: (1) the study must demonstrate more than

> doubling of the risk due to exposure (*i.e.*, a relative risk of greater than 2.0), (2) the study must have a confidence interval that does not include 1.0, and (3) the study must have a confidence (or significance) level of at least 95 percent. Furthermore, the court held isolated case reports and random experience to be insufficient and that an expert cannot dissect a study, picking and choosing data, or reanalyze the data to derive a higher relative risk. Additionally, the submission of a single epidemiological study without more is insufficient to establish causation.

Burton v. Wyeth-Ayerst Labs. Division of Am. Home Prods. Corp., 513 F. Supp. 2d 719, 730-31 (N.D. Tex. 2007) (internal citations and quotation marks omitted).

In *Garza*, the plaintiffs argued that they did not need to meet the *Havner* standard to establish that Vioxx caused their decedent's heart attack. Under the plaintiffs' view, the *Havner* standard should not apply to evidence from clinical trials, and *Havner* did not create a "bright line" rule requiring at least two epidemiological studies establishing a statistically significant doubling of risk in all cases. 347 S.W.3d at 262. The court rejected both of these arguments, reiterating and re-affirming its decision in *Havner*:

> *Havner* holds, and we reiterate, that when parties attempt to prove general causation using epidemiological evidence, a threshold requirement of reliability is that the evidence ***demonstrate a statistically significant doubling of the risk***. In addition, *Havner* requires that a plaintiff show that he or she is similar to [the subjects] in the studies and that other plausible causes of the injury or condition that could be negated [are excluded] with reasonable certainty. *Havner* also requires that even if studies meet the threshold requirements of reliability, sound methodology still necessitates that courts examine the design and execution of epidemiological studies using factors like the Bradford Hill criteria to reveal any biases that might have skewed the results of a study, and to ensure that the standards of reliability are met in ***at least two properly designed studies***.

Id. at 265-66 (internal quotations and citations omitted) (emphasis added).

Having reaffirmed the standards for epidemiological evidence of causation, the court then analyzed the studies presented by the plaintiff under those standards. It first rejected a study demonstrating a relative risk of approximately five on the grounds that the study used a higher

dose of Vioxx for a longer duration than the plaintiffs' decedent did. *Id.* at 266. The court then found that a second study could not support causation on the grounds that the study was a meta-analysis which "combine[d] the results of a number of different studies, with differing dosages, durations, and comparison drugs." *Id.* at 267. The court rejected a third study on the grounds that it found a relative risk of 1.92 rather than 2.0, and because the duration of the study was greater than the decedent's use. *Id.* Finally, the court found that a fourth study, which may have otherwise met the *Havner* requirements, could not suffice on general causation because "even if [it] qualifies under *Havner's* test, it cannot do so alone. Another study is still necessary, but lacking here." *Id.*

B. The *Havner*/*Garza* Standard is a Substantive Texas Law Requirement Which Governs Plaintiffs' Claims

The Fifth Circuit recently has held that *Havner* creates substantive requirements of Texas law, which must be applied by a federal court sitting in diversity. In *Wackman v. Rubsamen*, 602 F.3d 391 (5th Cir. 2010), the court first noted that "a federal court sitting in diversity, as we are here, must refer to state law for the kind of evidence that must be produced to support a verdict. *Id.* at 400 (internal quotation marks and citation omitted). Applying this rule, the court then held that the *Havner* standards must be applied to determine the type of evidence necessary to sustain a verdict, noting that "a plaintiff must rule out other plausible causes of the injury. *See Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997)." *Id.* In another decision earlier this year, the Fifth Circuit expressly held that the *Havner* requirements for epidemiological evidence applied in a diversity case applying Texas law:

> The plaintiffs attempted to use epidemiological studies to establish that their overexposure to radiation caused their physical harms. The Texas Supreme Court has held that epidemiological studies can be used "to raise a fact issue on

> causation" only if three conditions are met: (1) the studies are scientifically reliable and show a "substantially elevated risk," (2) the claimant is "similar to those in the studies," and (3) "if there are other plausible causes of the injury or condition that could be negated, the plaintiff must *offer evidence excluding those causes with reasonable certainty.*" *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997) (emphasis added).

Cotroneo v. Shaw Environment & Infrastructure, Inc., 639 F.3d 186, 193 (5th Cir. 2011).

The Texas Federal District Courts have likewise repeatedly held that *Havner* constitutes a substantive requirement of Texas causation law, and accordingly must be applied in diversity actions. For example, in *Wells v. Smithkline Beecham Corp*., No. A-06-CA-126-LY, 2009 WL 564303 (W.D. Tex. Feb. 18, 2009), *affirmed* 601 F.3d 375 (5th Cir. 2010), the court held that "*Havner* establishes substantive Texas law on plaintiff's causation burden of proof," and therefore applied the *Havner* standard in ruling on a motion for summary judgment. *Id.* at *8. Similarly, in *Burton*, the court "agree[d] with the conclusion reached by other federal courts that have addressed the issue: *Havner's* standards are substantive, not procedural, requirements." 513 F. Supp. 2d at 730 n.12 (citing *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814 (W.D. Tex. 2005)); *see also Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662, 669 (N.D. Tex. 2010) ("in ruling on the motion for summary judgment the court will consider the sufficiency of the epidemiological studies under the standards set forth in *Havner*").

Although it appears that no court has yet addressed this issue with respect to the Texas Supreme Court's recent decision in *Garza,* in which the Texas Supreme Court expressly "reiterated" and applied its decision in *Havner*, the same reasoning plainly applies, mandating that *Garza* be treated as a substantive Texas law requirement.

C. Plaintiffs Cannot Meet the *Havner*/*Garza* Standard

Plaintiffs' sole causation expert, Dr. Glass, has admitted that he does not present evidence sufficient to meet the *Havner/Garza* standard. Dr. Glass admitted that he is not aware of any epidemiological study demonstrating a statistically significant doubling of the risk of suicide or homicide associated with sertraline. (Glass Dep. at 148:5-11; 237:12-17.) Lacking such studies, Dr. Glass admittedly relies instead on uncontrolled, anecdotal case reports. (*Id.* at 160:16-23.) As *Havner* explicitly held, however, such anecdotal reports are insufficient to meet Plaintiffs' burden to establish causation. 953 S.W.2d at 720 (noting that FDA regulations "state that '[i]solated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered'" and that "courts should likewise reject such evidence because it is not scientifically reliable"). Accordingly, by Plaintiffs' sole causation expert's own admission, Plaintiffs cannot meet the *Havner*/*Garza* standard.

Indeed, Plaintiffs have identified only one study purporting to find a statistically significant doubling of risk in adult patients treated with ***any*** type of antidepressant medicine. *See* D. Fergusson et al., *Association Between Suicide Attempts and Selective Serotonin Reuptake Inhibitors: Systematic Review of Randomised Controlled Trials*, 330 BMJ 396 (2005) (Ex. 19). But this study cannot support general causation because it analyzed several distinct medications together as a group, and stated no finding as to sertraline specifically. *See id.* at 1 (noting that study purports to find an "association between suicide attempts and the use of SSRIs"); (Glass Dep. at 11:7-17.)

As such, the Fergusson study does not express any finding whatsoever as to Zoloft specifically, much less a finding that Zoloft is associated with a statistically significant doubling

of risk of suicide or homicide. The U.S. Court of Appeals for the Fifth Circuit and other courts have held that it is improper to extrapolate from data concerning a group of medications or chemical compounds to express a causation opinion as to a specific medication or compound. *See, e.g., Wells v. Smithkline Beecham Corp.*, 601 F.3d 375, 380 (5th Cir. 2010) (finding that study could not support general causation because it "represented a class association, as opposed to a specific medication, finding"); *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 353 (5th Cir. 2007) (finding that study could not support general causation because the "study focused on organic solvents as a class, including a wide-range of chemicals to which appellants were never exposed"); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 830 (D.C. Cir. 1988) (even for drugs with similar chemical structures, extrapolation from effects of one compound to another could not by itself furnish sufficient foundation for conclusion that drug at issue caused claimed effects). Thus, the Fergusson study does not sustain Plaintiffs' burden on general causation.

Moreover, even if the Fergusson study could properly be counted as a study meeting the *Havner*/*Garza* requirements, it would not be sufficient, standing alone, to sustain Plaintiff's burden. *E.g.*, *Garza*, 347 S.W.3d at 267. The court was presented with a similar situation in *Wells*. There, the plaintiff had presented a single study which arguably met "*Havner's* statistical requirements in that its results establish a relative risk of greater than two at a 95% confidence level, with a confidence interval that does not include one." 2009 WL 564303, at *11. However, the court found that the study could not sustain plaintiff's burden because "alone it is insufficient to establish general causation." *Id.* (*citing Havner*, 953 S.W.2d at 718, 727). Finding the plaintiffs' evidence insufficient to raise a material fact on general causation under *Havner*, the court entered summary judgment in favor of the defendant. *Id.* at *12. Plaintiffs are unable to

establish general causation for the same reasons here, and this Court should likewise enter summary judgment in Defendants' favor.

III. THE LEARNED INTERMEDIARY DOCTRINE DEFEATS EACH OF PLAINTIFFS' INADEQUATE WARNING CLAIMS

Each of Plaintiffs' claims hinges on proving that Zoloft's warnings were inadequate and the inadequacy of these warnings caused Ms. Roberts to kill her family and commit suicide:

- Defective Design: "the product was defective and unreasonably dangerous because there was ***no warning*** that it could cause homicidal thoughts and actions or actual homicide, or that it could cause suicide in adults." (Dkt. #77, ¶55)(emphasis added)

- Failure to Warn: "Defendants ***failed to timely and reasonably warn*** of material facts regarding the safety and efficacy of Zoloft…" (Dkt. #77, ¶ 68) (emphasis added)

- Breach of Warranty: "Defendants were under a ***duty to disclose*** the defective or unsafe nature of Zoloft to physicians, the FDA, consumers and users, such as Decedent." (Dkt. #77, ¶ 102) (emphasis added)

- Negligence: "The product was placed on the market ***without warning*** the users of Zoloft that it might cause them to be homicidal or commit homicide or that it might cause adults to commit suicide." (Dkt. #77, ¶ 143) (emphasis added)

Because this is a suit involving prescription drugs based on a failure to warn, the learned intermediary doctrine applies. *Ebel v. Eli Lilly & Co.*, 536 F.Supp.2d 767, 773 (S.D. Tex. 2008); *accord In re Norplant Contraceptive Products Liab. Lit.*, 955 F.Supp. 700, 709 (E.D. Tex. 1997), *aff'd* 165 F.3d 374 (5th Cir. 1999).

The learned intermediary doctrine is a products liability defense that requires a drug manufacturer to warn only "the prescribing physician of any potential dangers that may result from the drug's use." *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974). A manufacturer of prescription drugs is not required to warn patients or end users, only prescribing doctors, because "only a physician would understand the propensities and dangers involved."

Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. App.—Corpus Christi 1973, writ ref'd n.r.e.); s*ee also Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 185 (Tex. 2004). The question therefore is whether the prescribing doctor was adequately warned.

To survive a motion for summary judgment based on the learned intermediary doctrine, a plaintiff must produce evidence that 1) a product's warning was inadequate; and 2) an adequate warning would have resulted in a physician not using or prescribing the product. *Technical Chemical Company v. Jacobs*, 480 S.W.2d 602 (Tex. 1972); *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco, 1993, reh'g denied).

Plaintiffs cannot meet their burden on either of these elements. First, the label was approved by the FDA and is presumed to be adequate under Texas law. Tex. Civ. Prac. & Rem. Code § 82.007(a). This presumption may be rebutted in certain limited circumstances, but Plaintiffs have no competent evidence that any of those circumstances apply here. Second, Dr. Glaser testified that the warning adequately informed him of the risks to be considered when prescribing the medication, and Plaintiffs have no expert testimony to support their claim that the warning is inadequate. Finally, Plaintiffs cannot show that the warning was the cause of Ms. Roberts' actions because there is no evidence that Dr. Glaser would not have prescribed Zoloft if a different warning had been given. Dr. Glaser stated that he was fully aware of the risks associated with Zoloft based on his own knowledge and personal experience and that he had not learned anything since July 2007 that gives him reservations regarding his decision to prescribe Zoloft for Ms. Roberts. Moreover, it was already his typical practice to closely monitor all patients, including adult patients, initiated on Zoloft. Therefore, the warning that was in fact

provided to Dr. Glaser could not be a cause of Ms. Roberts' actions of killing her husband and two children and then herself. Summary judgment is therefore required.

A. Under Texas Law, there is a statutory presumption that the FDA-approved label is adequate, and Plaintiffs have no competent evidence to rebut the presumption.

Plaintiffs claim the murders and suicide occurred because the warnings distributed with Zoloft were inadequate. (Dkt. #77). However, the FDA approved those warnings. (FDA-Approved Label and Insert for Zoloft, Ex. 16; 9/14/06 FDA Approval Ltr.[5]) Under Texas law, when an FDA-approved warning is distributed with a drug, there is a presumption that a pharmaceutical manufacturer is not liable for failure to provide an adequate warning. *See* Tex. Civ. Prac. & Rem. Code § 82.007(a). The presumption applies to claims for marketing defect, negligence, and breach of warranty. *Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F.Supp.2d 662, 675-76 (N.D. Tex. 2010) (dismissing plaintiffs' claims for marketing defect, breach of warranty, and negligence premised on failure to warn when statutory presumption of adequacy was not rebutted).

The presumption may be rebutted only if the plaintiff establishes that: 1) the manufacturer withheld information or made misrepresentations to the FDA during the pre-market approval process; 2) the drug was sold by the manufacturer after the FDA has recalled the product or withdrawn approval of the product; 3) the manufacturer marketed the product for an indication not approved by the FDA and the plaintiff actually used the product in that manner; or 4) the manufacturer violated 18 U.S.C. § 201 before or after pre-market approval, and that

[5] Available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/019839s058,%20019839s060,%20020990s024,%20020990s026ltr.pdf

violation caused the warnings or instruction approved by the FDA to be inadequate. Tex. Civ. Prac. & Rem. Code § 87.007(b). Plaintiffs have no evidence to establish any of these permissible grounds to rebut the presumption that the warnings were adequate.

B. The evidence establishes that the FDA-approved label is an adequate warning of the risks associated with Zoloft, and Plaintiffs have not raised a genuine fact issue that the warning was inadequate.

Even without the statutory presumption, the evidence establishes that the warning adequately informed Dr. Glaser of the risks associated with Zoloft. In his deposition, Dr. Glaser testified that the portion of the FDA-approved label titled "Clinical Worsening and Suicide Risk" was consistent with his understanding of the risks to both adults and pediatric patients using antidepressant medication. (Dep. of Dr. Glaser at 45:8-24, Ex. 15). He further admitted that the FDA-approved label appropriately conveyed to him the information required to make an appropriate risk/benefit analysis concerning Zoloft:

> Q. Do you believe that that label appropriately conveyed to you the information required to make an appropriate risk/benefit analysis concerning Zoloft?
>
> A. Yes.

(Dep. of Dr. Glaser 91:18-22, Ex. 15). Indeed, doctors "are in the best position to evaluate the warnings put out by the drug industry" because "laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists." *Gravis v. Parke Davis & Co.*, 502 S.W.2d 863, 870 (Tex. App.—Corpus Christi, 1973).

In contrast, Plaintiffs have no evidence to support their claim that the warning was inadequate. Their designated liability expert, Dr. Glass, admitted that he has no criticisms of the warnings and did not intend to offer any opinions regarding the adequacy of the warnings. (Dep.

of George S. Glass at 65: 22-24; 224:17-22, Ex. 7). Plaintiffs have no other expert testimony addressing the adequacy of the warning. "Expert testimony is required when an issue involves matters beyond jurors' common understanding." *Mack Trucks, Inc. v. Tamez*, 206 S.W.3d 572, 583 (Tex. 2006); *see also Alexander v. Turtur & Assocs., Inc.*, 146 S.W.3d 113, 119-20 (Tex. 2004). "Whether expert testimony is necessary to prove a matter or theory is a question of law." *Mack Trucks*, 206 S.W.3d at 583. In Texas, this has specifically meant that expert testimony is required to determine the adequacy of a pharmaceutical warning. *Hackett v. Searle*, 2002 U.S. Dist. LEXIS 16246, at *8 (W.D. Tex. 2002); *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 211-12 (Tex. App.—Dallas [5th Dist.] 2011, pet. filed).

The adequacy of a prescription drug label involves issues that are unfamiliar to the ordinary person. The Fifth Circuit recognized that "[p]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect" that require a "medical expert" who "can take into account the propensities of the drug, as well as the susceptibilities of his patient." *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974). Other courts have also recognized that "because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients." *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 503 (Tex. App.—Corpus Christi, 2010) (*quoting* Lars Noah, *This is Your Products Liability Restatement on Drugs*, 74 Brook. L. Rev. 839, 892 (2009). Moreover, Texas law typically "requires expert testimony to establish the standard of care in medical cases." *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d at 211.

Because Plaintiffs have no expert testimony demonstrating ***any*** inadequacy in the warning that was distributed with Zoloft, and the prescriber himself unequivocally testified that the warning appropriately conveyed to him sufficient information, their claims must fail.

C. Plaintiffs' claims fail because there is no evidence that Dr. Glaser would not have prescribed Zoloft had the warning been different.

In a failure to warn case, "even if we assume that the plaintiff can prove that the given warnings were inadequate, the plaintiff still must prove causation." *Wyeth-Ayerst Laboratories Co. v. Medrano*, 28 S.W.3d 87, 95 (Tex. App.—Texarkana, 2000). To prove causation, Plaintiffs "must show that a proper warning would have changed the decision" of Dr. Glaser to prescribe the product. *Id*.; *Guzman v. Synthes (USA)*, 20 S.W.3d 717, 720 (Tex. App.—San Antonio, 1999) ("Synthes argues there is no evidence tending to establish Dr. Bell would have treated Guzman differently had additional warnings been given. We agree.") If Plaintiffs fail to meet this burden then, as a matter of law, they have failed to prove causation. *Medrano*, 28 S.W.3d at 95.

There is no evidence that a different Zoloft warning would have caused Dr. Glaser to refrain from prescribing Zoloft. He has prescribed Zoloft many times for depressed patients and ***continues*** to prescribe Zoloft for appropriate patients. (Dep. of Dr. Glaser at 52:9-53:1; 59:18-20, Ex. 15). Furthermore, he believes that his decision to prescribe Zoloft for Ms. Roberts was appropriate. (*Id.* at 89:12-16). In fact, he testified that he has not learned anything since July 2007, when he prescribed the medication for Ms. Roberts, that gives him any reservations about his decision to give her Zoloft, and that he still would view Zoloft as an appropriate medication for her today:

> Q. And based on anything you've learned since July of 2007, is there anything that gives you any reservations about your decision to give her Zoloft?
> A. No.
> Q. And if Ms. Roberts or a patient—a patient like Ms. Roberts came into your office today with the same complaints that she presented to you, would you believe that Zoloft would still be an appropriate medication to prescribe for them?
> A. I don't know. I don't think – in theory it would be, but in my practice, it's probably not.
> Q. Okay, so theoretically it would be a fine medication to—to use for them, fair?
> A. Fair.

(*Id*. at 89:17-90:8.)

Dr. Glaser testified that he now has a "mental block" against using Zoloft, comparing the situation to one in which one avoids an intersection where an accident has occurred for irrational reasons. (Glaser Dep. at 91:3-13.) This fact, however, does not alter the summary judgment analysis because Dr. Glaser readily admitted that this irrational thought was the only reason he might not prescribe Zoloft today, and further admitted that there is no medical or scientific basis for his reluctance to use Zoloft:

> Q. Aside from what we've discussed as your sort of mental block against using Zoloft, is there any other reason why you would not use Zoloft as an appropriate treatment for a patient like Ms. Roberts today?
> A. No.
> Q. Is it fair to say that there is no medical or scientific information of which you've become aware that would make you think that Zoloft would not be an appropriate treatment for Ms. Roberts today?
> A. For depression/anxiety, no.

(*Id.* at 92:14-93:15.) Thus, there is no evidence to support a contention that a different warning would have altered Dr. Glaser's decision to prescribe Zoloft. Accordingly, Plaintiffs have no evidence that a different warning would have changed Dr. Glaser's decision to prescribe Zoloft, so the warning could not be a cause of Plaintiffs' injuries.

Moreover, a warning, whether adequate or inadequate, is not a producing or proximate cause of a patient's injury when the physician is fully aware of the risks associated with the drug, and chooses to prescribe it. *See Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex. App.—El Paso [8th Dist.] 1989). Dr. Glaser testified that he was aware of the need to closely monitor all patients for emergence of suicidality upon initiation of Zoloft, and that he did in fact monitor Roberts "[a]s is typical in [his] practice for initiating the (sic) Zoloft." (Glaser Dep. 46:7-48:4, Ex. 15). Accordingly, any purported warning inadequacy cannot have been the cause of Plaintiffs' injuries because it is undisputed that Dr. Glaser was aware of the need to monitor all patients started on Zoloft for the emergence of suicidal behavior. In other words, because Dr. Glaser was aware of the risks associated with the medication regardless of the warning and still chose to prescribe it, as a matter of law, the adequacy of the warning was not a proximate or producing cause of Plaintiffs' injuries.

CONCLUSION

For the reasons set forth above, summary judgment should be entered for Defendants on all of Plaintiffs' claims.

Dated: December 23, 2011

Respectfully submitted,

s/ Andrew Myers

John H. Martin, Esq.
Thompson & Knight – Dallas
1722 Routh Street, Suite 1500
Dallas, TX 75201-2533
Telephone No. (214)969-1229\
Facsimile No. (214)969-1751

James E. Hooper, Esq.
Email: hooper@wtotrial.com
Andrew H. Myers, Esq.
Email: myers@wtotrial.com
Theresa R. Wardon, Esq.
Email: wardon@wtotrial.com
Wheeler Trigg O'Donnell LLP
1801 California Street, Suite 3600
Denver, CO 80202-2817
Telephone No. 303-244-1800
Facsimile No. 303-244-1879

Attorneys for Defendants

CERTIFICATE OF SERVICE (CM/ECF)

I HEREBY CERTIFY that a true and correct copy of **DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT WITH SUPPORTING AUTHORITIES** was served via manner indicated below this 23 day of December, 2011 to the following:

Thomas M. Corea, Esq.
Jessica S. Graham, Esq.
The Corea Firm PLLC
The Renaissance Tower
1201 Elm Street, Suite 4150
Dallas, TX 75270
Telephone: 214-953-3900
Facsimile: 214-953-3901

Attorneys for Plaintiffs

( ) First Class Mail
( ) Hand Delivery
( ) Facsimile
( ) Overnight Delivery
(x) E-mail via Electronic Filing System

s/ Andrew Myers